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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/912,122

07/24/2001

Joshua Makower

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EXAMINER

SWEET, THOMAS

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/912,122		<b>Applicant(s)</b> MAKOWER ET AL.	
	<b>Examiner</b> Thomas J. Sweet		<b>Art Unit</b> 3774	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 21 July 2008.

2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 53-58 and 61-63 is/are pending in the application.

    4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 53-58 and 61-63 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All    b) ☐ Some \*    c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
    Paper No(s)/Mail Date \_\_\_\_\_.

4) ☐ Interview Summary (PTO-413)  
    Paper No(s)/Mail Date \_\_\_\_\_.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments, see page 4, filed 6/23/2008, with respect to claim objection have been fully considered and are persuasive. The objection of claim 53 has been withdrawn.

Applicant's arguments filed 23 June 2008 have been fully considered but they are not persuasive. Applicant is arguing intended use with respect to a radiopaque markers. Use of radiopaque markers is routine in the catheter arts as evidence by US 5749848 (intrinsic evidence of record in the case). The prior art rejection is fully capable of the intended use and radiopaque marks are inherent being so conventional that the prior art need not explain there use beyond stating "positioning".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 53-58 and 61-63 are rejected under 35 U.S.C. 102(a and e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Faxon et al (US 5464395) and Jang et al (US 5749848 intrinsic evidence of record). Faxon et al discloses a system (fig. 2) that is useable to guide the advancement of a guidewire (45) from a location within the lumen of a blood vessel to a target location within or outside of the wall of that blood vessel (col 1 lines 12-16), said system comprising:

- an elongate flexible catheter body (10) that is advanceable through the vasculature into said blood vessel lumen (col 1, lines 12-16), said catheter body having a side wall and at least one lumen extending longitudinally therethrough (at 55);

- an opening formed in the side wall of said catheter body (at 65);

- a single tissue penetrating element (80) having a lumen (100), a tissue penetrating distal tip (90) and a distal end opening (95), said tissue penetrating element being alternately disposable in;

- a) a first position wherein the tissue penetrating element is substantially within the catheter body (fig. 2); and

- b) a second position wherein the tissue penetrating element assumes a predetermined curved configuration and extends out of the opening formed in the side wall of said catheter body so as to penetrate a wall of the blood vessel adjacent to the blood vessel lumen in which the catheter is positioned (fig. 1); and

a guidewire (45) that is advanceable through the lumen of the tissue penetrating element while the tissue penetrating element is in the second position; and

inherently (as a matter of routine in the art, as supported by intrinsic evidence of record-Jang et al) one or more imageable (such as radiopaque) markers useable in conjunction with an imaging apparatus (such as by fluoroscope x-ray) to facilitate adjustment of the rotational orientation of the catheter body within the blood vessel so that subsequent advancement of the tissue penetrating element will cause the tissue penetrating element to advance in the direction of the target location. If the marker and imager are not considered inherent, it is well known in the art to image a catheter using radiopaque markers and a fluoroscope to view and guide a catheter and therefore would have been obvious.

Regarding claims 54-57, an anchoring member (balloon, 25), said anchoring member being deployable when the catheter body is inserted into an anatomical lumen such that a surface of the anchoring member will engage a wall of the anatomical lumen thereby preventing at least a portion of the catheter body from undergoing substantial movement within the anatomical lumen.

Regarding claims 62-63, the imaging apparatus comprises an intravascular ultrasound imaging apparatus (the surface of the guidewire, 45) and the catheter body has a lumen (15) into which the imaging apparatus is inserted (the guide wire is inherently capable of being imaged intravascularly and is received in a lumen, the breadth of the claim does not limit the imaging apparatus to a transducer, which is well known in the art but not claimed).

***Conclusion***

This is a RCE. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:45am - 5:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3774

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas J Sweet/  
Primary Examiner, Art Unit 3774